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| EXAMINER | |
|---|---|
| CHOWDHURY, IQBAL HOSSAIN | |
| ART UNIT | PAPER NUMBER |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/529,366 | EULENBERG ET AL. | |
| | Examiner | Art Unit | |
| | IQBAL H. CHOWDHURY | 1652 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *18 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) *2-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *03/28/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Status*

Claims 1-33 are currently pending in the instant application.

This application is a 371 of PCT/EP03/10799.

The preliminary amendment filed on March 28, 2005, amending claims 4-8, 10-15, 19, 25-29 and 31 is acknowledged.

### *Election/Restriction*

Applicant's election with traverse of Group III, Claims 1 and 33, drawn to a composition comprising a modulator/effector molecule of a nucleic acid molecule with an identification number of CG7042, which comprises a cDNA (GenBank Accession No. NM_080876) encoding a protein SKRP1 (stress-activated protein kinase pathway-regulating phosphatase 1) having dual-specificity phosphatase activity and a kit comprising said modulator, and an invention of a human gene encoding a protein of SKRP (NM_080876) in the response filed on September 18, 2007 is acknowledged.

The traversal is on the ground(s) that examination of Group III with Group VII (drawn to a method of making a medicament by using modulator of a nucleic acid molecule) would be no burden of search for the coexamination of the groups III and VII simultaneously, as they are linked to form a single general inventive concept.

This is not found persuasive because elected Group III is drawn to a product but Group VII is drawn to a method of use of said product. As discussed previously in the restriction requirement (mailed on 5/18/2007), the inventions of Groups I-XIX, do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the

same or corresponding special technical feature because the technical feature linking Groups I-XIX appears to be that they all relate to nucleic acids or proteins involved in the regulation of energy homeostasis. However, the nucleic acids and proteins involved in the regulation of energy homeostasis were known in the art. For example, Mayers et al. (2001) teach a dual specificity phosphatase protein (same as instant application) and uses thereof, which is known in the art (that is the elected gene encoding protein). Thus, a DNA or protein and uses thereof, does not make contribution over the prior art. Therefore, all the Groups lack unity of invention. Besides, while the search necessary for examination of all the groups overlaps it is not coextensive, examination of Group VII would require search of subclasses unnecessary for the search of Group III.

Applicants further traverse for electing inventions i.e. one of the cDNA set forth in Table 1, wherein the elected cDNA is for human SKRP protein (NM_808076) without any argument. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement of the cDNA of Table 1, the election has been treated as an election without traverse (MPEP § 818.03(a)).

In addition, examining Group VII and all the cDNAs of Table 1 with elected Group III and SKRP cDNA, would create a serious search burden to the Office. Furthermore, the search is not limited to only patent database but also includes large non-patent databases. Searching Groups III and VII as well as all the cDNAs, and analyzing the vast search results from both patent and non-patent databases imposes a serious search burden on the Examiner. As restriction is clearly permissible even among related inventions as defined in MPEP 808 and 35 U.S.C. 121 allows restriction of inventions, which are independent or distinct.

The requirement is still deemed proper and is therefore made FINAL.

Claims 2-32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention. Applicant timely traversed the restriction (election) requirement in communication filed on 9/18/2007.

Claims 1 and 33 are under consideration and are being examined herein.

### *Priority*

Acknowledgement is made of applicants claim for foreign priority of application EP 02021916.8 filed on 9/27/2002.

### *Information Disclosure Statement*

The information disclosure statement (IDS) submitted on 3/28/2005 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is considered by the examiner. The signed copy of IDS is enclosed herewith.

### *Drawings*

Drawings submitted on 3/28/2005 are accepted by the Examiner.

### *Claim Objections*

Claims 1 and 33 are objected to as encompassing non-elected subject matter. Appropriate correction is requested.

Claims 1 and 33 are objected to in the recitation CG7042; as abbreviations should not be

used without at least once fully setting forth what they are used for. Appropriate correction is required.

***Claim Rejections - 35 USC § 112 (2nd)***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1 and 33 are drawn to a pharmaceutical composition comprising a modulator/effector of said nucleic acid molecule, wherein said nucleic acid molecule encodes a CG7042 protein or/and a functional fragments thereof, or a kit comprising said modulator, which modulates said nucleic acid molecule, which is confusing. What is CG7042? Is it a nucleic acid molecule or something else? The Examiner assumes that CG7042 is an identification number of a cDNA (GenBank Accession No. NM_808076) encoding a protein SKRP1 (stress-activated protein kinase pathway-regulating phosphatase 1) having dual-specificity phosphatase activity. Clarification is required.

Claims 1 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite and vague for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the present instance, claim 1 drawn to "A pharmaceutical composition comprising a modulator/effector molecule of nucleic acid molecule of CG7042, which is corresponding to a GenBank Accession No. NM_808076 (see response of dated 9/18/2007), and a kit comprising said GenBank Accession No. NM_808076, which is confusing. What is CG7042? Is it a nucleic acid molecule or something else? The Examiner assumes that

CG7042 is an identification number of a cDNA (GenBank Accession No. NM_808076) encoding a protein SKRP1 (stress-activated protein kinase pathway-regulating phosphatase 1) having dual-specificity phosphatase activity. However, GenBank accession number is also indefinite because as known in the art, entries in GenBank can maintain the accession number even if there are modifications in the sequence. Therefore, CG7042, which is correspond to the GenBank accession number renders the instant claims indefinite in view of the fact that the sequence in the accession number may vary. In fact the same GenBank Accession No. NM_808076 has two gi numbers, 1) 1825447 (1275 bp mRNA) and 2) 31377625 (5183 bp mRNA), i.e. the two cDNAs are completely different (see attached gi document). It is unclear as to which sequence is referred to by the applicants as CG7042. Clarification is required.

***Claim Rejections - 35 USC § 112 (1st, Written description)***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1 and 33 are directed to drawn to a pharmaceutical composition comprising a modulator/effector molecule of a nucleic acid molecule with identification number of CG7042

that comprises a cDNA (GenBank Accession No. NM_080876) encoding a human protein SKRP1 (stress-activated protein kinase pathway-regulating phosphatase 1) or/and a functional fragments thereof having dual-specificity phosphatase activity and a kit comprising said modulator.

The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." University of California v. Eli Lilly and Co., 1997 U.S. App. LEXIS 18221, at *23, quoting Fiers v. Revel, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these (paraphrased from *Enzo Biochemical*).

Thus, Claims 1 and 33 are directed to a composition comprising any modulator/effector molecule of any nucleic acid molecule of GenBank Accession No. NM_080876 having two sequences encoding a human polypeptide or/and a functional fragments thereof and a kit comprising said modulator, wherein said modulators and said nucleic acids structures are not fully described in the specification. No information, beyond the characterization that said modulator modulates any nucleic acid molecule of GenBank Accession No. NM_080876

encoding a protein or/and a fragments thereof, which would indicate that applicants had possession of the claimed genus of any modulator of any nucleic acid molecule of GenBank Accession No. NM_080876, which includes fragments, variants and analogues. The specification does not contain any disclosure of the structure of all the fragments, variants or analogues of any modulator, which modulates any nucleic acid molecule of GenBank Accession No. NM_080876. The genus of any modulator, which includes any aptamers, any antisense molecules, any RNAi molecules, or any ribozymes of any nucleic acid molecule of GenBank Accession No. NM_080876 is a large variable genus including many fragments, variants and analogues, which can have wide variety of structures. Therefore, many structurally unrelated modulators are encompassed within the scope of the claims. The specification does not disclose any representative species of the claimed genus, i.e. any modulator, which includes any aptamers, any antisense molecules, any RNAi molecules, or any ribozymes of any nucleic acid molecule of GenBank Accession No. NM_080876, which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that applicant had possession of the claimed invention at the time the instant application was filed.

In addition, the specification discloses two representative species of the claimed genus of GenBank Accession No. NM_080876 modulated by the modulator, which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

***Claim Rejections - 35 USC § 112 (1st, Scope of Enablement)***

Claims 1 and 33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a pharmaceutical composition comprising two nucleic acid molecules encoding a polypeptide SKRP1 having dual-specificity phosphatase from human and expression of mRNA of said nucleic acid molecule having dual-specificity phosphatase activity, does not reasonably provide enablement for a pharmaceutical composition comprising any modulator/effector molecule of any nucleic acid molecule of GenBank Accession No. NM_080876 encoding a polypeptide or/and a functional fragments thereof having dual-specificity phosphatase activity and a kit comprising said modulator. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required are summarized in In re Wands (858 F.2d 731,737, 8 USPQ2nd 1400 (Fed. Cir. 1988)) as follows:

(1) quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence and absence of working examples, (4) the nature of the invention, (5) the state of prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The factors, which have, lead the Examiner to conclude that the specification fails to teach how to make and/or use the claimed invention without undue experimentation, are addressed below:

***The breadth of the claims:***

Claims 1 and 33 are so broad as to encompass a pharmaceutical composition comprising any unknown modulator/effector molecule of any nucleic acid molecule of GenBank Accession No. NM_080876 encoding a polypeptide SKRP1 or/and any functional fragments thereof having dual-specificity phosphatase activity and a kit comprising said modulator.

The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of modulators of any nucleic acid molecule of GenBank Accession No. NM_080876 encoding a polypeptide SKRP or/and a functional fragments thereof having dual-specificity phosphatase activity for making said composition and a kit comprising said modulator broadly encompassed by the claims. The modulators of nucleic acids includes any aptamers, any antisense molecules, any RNAi molecules, or any ribozymes of said nucleic acid molecule, which requires a knowledge of and guidance with regard to which modulators to be used and detailed knowledge of the ways in which the modulators structure relates to its function. However, in this case the disclosure is not limited to structure of any modulators of said nucleic acid but rather the generic names of any aptamers, any antisense molecules, any RNAi molecules, or any ribozymes. The specification fails to provide sufficient teaching such as unifying common feature, or structural and functional relationship, of any modulators for successful use, which would allow predicting from different structures.

***The amount of direction or guidance presented and the existence of working examples:***

The specification discloses two nucleic acid molecules encoding a polypeptide SKRP1 having dual-specificity phosphatase from human and expression of mRNA of said nucleic acid molecule. However, the specification fails to provide any clue as to the structural elements required in any modulator/effector molecule of any nucleic acid molecule of GenBank Accession

No. NM_080876 encoding a polypeptide SKRP1 or/and any functional fragments thereof having dual-specificity phosphatase activity to be used in making a pharmaceutical composition and a kit comprising said unknown modulator, or which are the structural elements in said modulators or the nucleic acid molecules to be used in the claimed composition and kit known in the art that are essential for successfully practice the claimed invention. No correlation between structure and function has been presented.

The specification does not support the broad scope of the claims, which encompass a pharmaceutical composition comprising any modulator/effector molecule of any nucleic acid molecule of GenBank Accession No. NM_080876 encoding a polypeptide SKRP1 or/and a functional fragments thereof having dual-specificity phosphatase activity and a kit comprising said modulator and the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including a pharmaceutical composition comprising any modulator/ effector molecule of any nucleic acid molecule of GenBank Accession No. NM_080876 encoding a polypeptide SKRP1 or/and a functional fragments thereof having dual-specificity phosphatase activity and a kit comprising said modulator. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, making a pharmaceutical composition or a kit comprising any modulator/effector molecule of any nucleic acid molecule of GenBank Accession No. NM_080876 encoding a polypeptide SKRP1 or/and a functional fragments thereof having dual-

specificity phosphatase activity having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Tang et al. (WO 01/81590, Protein phosphatases, publication 11/1/2001, see IDS). Instant claim is drawn to a pharmaceutical composition comprising any modulator/effector molecule of any nucleic acid molecule of GenBank Accession No. NM_080876 encoding a polypeptide or/and a functional fragments thereof having dual-specificity phosphatase activity together with pharmaceutical acceptable carriers, a kit comprising said modulator.

Tang et al. teach a pharmaceutical composition comprising an agonist or antagonist of nucleic acid molecule encoding a polypeptide of 217 amino acids having dual specificity phosphatase activity, which is 100% identical to the protein encoded by the nucleic acid molecule (cDNA) of the instant application, wherein said antagonist is antisense molecule (see page 26, 43-44) of the coding region or regulatory region of said nucleic acid molecule that can be used for therapeutic purpose. Claim 33 is included in this rejection because a kit comprising said modulator of nucleic acid molecule is indeed a modulator of said nucleic acid molecule.

Tang et al. anticipate claim 33 because Tang et al. teach a modulator of said nucleic acid molecule and a pharmaceutical composition for use in therapy. Therefore, Tang et al. anticipate claims 1 and 33 of the instant application.

***Conclusion***

**Status of the claims:**

Claims 1-33 are pending.

Claims 2-32 are withdrawn.

Claims 1 and 33 are rejected.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iqbal Chowdhury whose telephone number is 571-272-8137. The examiner can normally be reached on 9:00-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat T. Nashed can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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